K090967

510(k) SUMMARY

1. Submitted By:

BD Biosciences
2350 Qume Drive
San Jose, CA 95131-1807

JUL 31 2009

Contact:
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Submission date: April 3, 2009

2. Device Name and Classification:

a) BD Multitest™ 6-color TBNK Reagent
b) 21 CFR 864.5220, Automated differential cell counter, GKZ, Class II

3. Currently Marketed Predicate Device:

BD Multitest™ 6-Color TBNK with Trucount™ Tubes [510(k) # K060375]

4. Intended Use:

BD Multitest 6-color TBNK reagent with optional BD Trucount™ tubes is a six-color direct immunofluorescence reagent for use with BD FACSCanto™ and BD FACSCanto™ II flow cytometers to identify and determine the percentages and absolute counts of T, B, and natural killer (NK) cells as well as the CD4 and CD8 subpopulations of T cells in peripheral blood.

BD Multitest 6-color TBNK reagent and BD Trucount tubes can be used with the BD FACS™ Loader.

5. Basic description of the device:

Human lymphocytes can be divided into three major subset populations based on their biologic function and cell-surface antigen expression: T lymphocytes (CD3+), B lymphocytes (CD19+), and Natural Killer (NK) cells (CD16+ and/or CD56+). CD3+ T lymphocytes can be further divided into CD4+ T lymphocytes and CD8+ T lymphocytes.

BD Multitest 6-Color TBNK Reagent is a monoclonal antibody cocktail of CD3-FITC/ CD16-PE + CD56-PE/ CD45-PerCP-Cy5.5/ CD4-PE-Cy7/ CD19-APC/ CD8-APC-Cy7.

When the reagent is used to stain a known volume of whole blood, the fluorochrome-labeled antibodies in the reagent bind specifically to leucocyte surface antigens. The stained samples are treated with BD FACS™ Lysing Solution to lyse erythrocytes prior to acquisition and analysis on the BD FACSCanto or BD FACSCanto II flow cytometer. During acquisition, the cells travel past two spatially separated laser beams. The cells scatter the laser light and the cell-bound fluorochrome-labeled antibodies fluoresce. These scatter and fluorescence signals are detected by the flow cytometer and provide information about the cell's relative size, internal complexity and fluorescence intensity. During analysis by BD FACSCanto clinical software, the lymphocyte population percentages are determined. Lymphocyte population absolute counts may be determined if lymphocyte data from another method is manually entered.

6. Comparison to the Predicate:

The content and intent of the intended use and indications of BD Multitest 6-Color TBNK Reagent, as described in its labeling, are the same as the intended use and indications of the original predicate device. The fundamental scientific technology also remains the same. In addition, BD Multitest 6-Color TBNK Reagent is substantially equivalent to the predicate (K060375) in:

- Clinical Application
- Monoclonal antibody reagent composition
- Instrument used

The modification enables the use of BD Trucount tubes to be optional. The use of the reagent without BD Trucount Tubes may be more appropriate for those clinicians who need only lymphocyte population percentages or who prefer to use lymphocyte data from another method to determine lymphocyte population absolute counts.

Performance studies confirm that the devices are substantially equivalent in performance characteristics and the device modification does not raise any unresolved issues of safety or efficacy.

7. Summary of Performance Data:

Performance study data from testing supported the determination of substantial equivalence. Performance testing to support substantial equivalence included clinical and non-clinical studies. Clinical testing was done for precision and method comparison to the predicate. Non-clinical testing was done for method comparison, functionality and file-based equivalency.

Clinical Precision:

Lymphocyte population percentages met the predetermined acceptance criteria: the upper one-sided 95% confidence bound on the standard deviation (SD) for the within-device precision must be ≤2.5 on the investigational system.

Clinical Method Comparison:
Lymphocyte population percentages, in comparison to the predicate, met the predetermined acceptance criteria: the 95% confidence interval (CI) of the mean difference between the investigational and predicate systems must be within an absolute ±3% or a relative ±10% of the predicate mean, whichever is greater.

Non-Clinical Method Comparison:
Lymphocyte population percentages, in comparison to the predicate, met the predetermined acceptance criteria: the 95% CI of the mean difference between the test and predicate population shall be within +/-3% absolute or +/-10% relative to the predicate mean, whichever is greater.

Non-Clinical Software Functionality:
BD FACSCanto clinical software version 2.4 met the predetermined functional requirements for software development (including functionality such as cytometer setup & optimization, acquisition/analysis worklist, Lab Manager, user preferences, running a QC sample, and user interface).

Non-Clinical File-Based Equivalency for Software:
BD FACSCanto clinical software version 2.4 met the predetermined functional requirements for providing results equivalent to the results from the previously released version of the software, (BD FACSCanto clinical software version 2.2).

This 510(k) Summary is being submitted in accordance with the requirements of compliance with SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

BD Biosciences
c/o Katy Campbell
Regulatory Affairs Specialist
2350 Qume Drive
San Jose, California 95131-1807

JUL 31 2009

Re: k090967
Trade Name: BD Multitest™ 6-color TBNK Reagent with Trucount™ Tubes
Regulation Number: 21 CFR §864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Codes: GKZ
Dated: July 22, 2009
Received: July 23, 2009

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

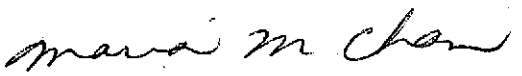
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090967

Device Name: BD Multitest™ 6-color TBNK Reagent

Indication For Use:
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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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